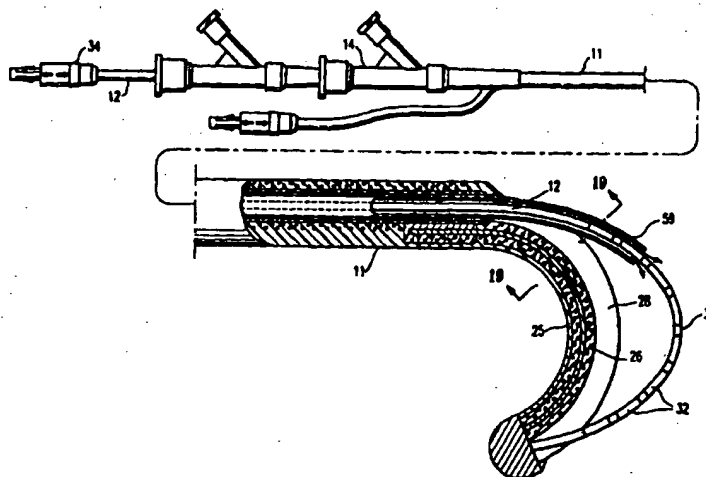




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | |
|---|--|---|
| (51) International Patent Classification ⁶ : A61B 18/14, A61M 25/01 | A2 | (11) International Publication Number: WO 97/37607 (43) International Publication Date: 16 October 1997 (16.10.97) |
| <p>(21) International Application Number: PCT/US97/05714</p> <p>(22) International Filing Date: 8 April 1997 (08.04.97)</p> <p>(30) Priority Data: 08/629,057 8 April 1996 (08.04.96) US 08/659,769 6 June 1996 (06.06.96) US</p> <p>(71) Applicant: CARDIMA, INC. [US/US]; 47266 Benicia Street, Fremont, CA 94538 (US).</p> <p>(72) Inventor: SCHAER, Alan, K.; 10162 Alpine Drive #B, Cupertino, CA 95014 (US).</p> <p>(74) Agents: LYNCH, Edward, J.; Heller Ehrman White & McAuliffe, 525 University Avenue, Palo Alto, CA 94301-1900 (US) et al.</p> | <p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>Without international search report and to be republished upon receipt of that report.</i></p> | |

(54) Title: **LINEAR ABLATION DEVICE AND ASSEMBLY**

(57) Abstract

An intravascular device for the formation of linear lesions which has particular utility in the treatment of atrial fibrillation and flutter. The intravascular device has an outer delivery sheath (11) with a distal section (25) which has an elongated opening (28) and a support member (26) coextending with the opening (28). An EP device (12) having a plurality of electrodes (32) on its distal portion (31) is slidably disposed within the inner lumen (13) of the delivery sheath (11) but it is secured by its distal end within the distal extremity of the delivery sheath (11) at least while in operation. In this manner an axial force in the distal direction on the proximal extremity of the EP device (12), which extends out of the patient during the procedure, will cause the distal portion of the EP device (12) to arch outwardly out of and away from the distal section (25) of the delivery sheath (11) and engage the surface of the patient's heart chamber. High frequency, e.g. RF, electrical energy delivered to the electrodes (32) on the distal shaft section (31) of the EP device (12) will form a linear lesion which terminates the fibrillation or flutter.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | | | | | | |
|----|--------------------------|----|--|----|--|----|--------------------------|
| AL | Albania | ES | Spain | LS | Lesotho | SI | Slovenia |
| AM | Armenia | FI | Finland | LT | Lithuania | SK | Slovakia |
| AT | Austria | FR | France | LU | Luxembourg | SN | Senegal |
| AU | Australia | GA | Gabon | LV | Latvia | SZ | Swaziland |
| AZ | Azerbaijan | GB | United Kingdom | MC | Monaco | TD | Chad |
| BA | Bosnia and Herzegovina | GE | Georgia | MD | Republic of Moldova | TG | Togo |
| BB | Barbados | GH | Ghana | MG | Madagascar | TJ | Tajikistan |
| BE | Belgium | GN | Guinea | MK | The former Yugoslav Republic of Macedonia | TM | Turkmenistan |
| BF | Burkina Faso | GR | Greece | | | TR | Turkey |
| BG | Bulgaria | HU | Hungary | ML | Mali | TT | Trinidad and Tobago |
| BJ | Benin | IE | Ireland | MN | Mongolia | UA | Ukraine |
| BR | Brazil | IL | Israel | MR | Mauritania | UG | Uganda |
| BY | Belarus | IS | Iceland | MW | Malawi | US | United States of America |
| CA | Canada | IT | Italy | MX | Mexico | UZ | Uzbekistan |
| CF | Central African Republic | JP | Japan | NE | Niger | VN | Viet Nam |
| CG | Congo | KE | Kenya | NL | Netherlands | YU | Yugoslavia |
| CH | Switzerland | KG | Kyrgyzstan | NO | Norway | ZW | Zimbabwe |
| CI | Côte d'Ivoire | KP | Democratic People's Republic of Korea | NZ | New Zealand | | |
| CM | Cameroon | | | PL | Poland | | |
| CN | China | KR | Republic of Korea | PT | Portugal | | |
| CU | Cuba | KZ | Kazakhstan | RO | Romania | | |
| CZ | Czech Republic | LC | Saint Lucia | RU | Russian Federation | | |
| DE | Germany | LI | Liechtenstein | SD | Sudan | | |
| DK | Denmark | LK | Sri Lanka | SE | Sweden | | |
| EE | Estonia | LR | Liberia | SG | Singapore | | |

LINEAR ABLATION DEVICE AND ASSEMBLY

BACKGROUND OF THE INVENTION

This invention generally relates to the detection and elimination
5 of cardiac arrhythmia and particularly atrial fibrillation.

Atrial fibrillation is the disorganized depolarization of a patient's atrium with little or no effective atrial contraction. This condition may be chronic or intermittent, and it affects up to 2 million or more people in the United States alone. For atrial fibrillation refractory to conventional
10 drug therapy, it has been conventional practice to make incisions in the atrial wall, to surgically segregate the tissue thereof, to discontinue the atrial fibrillation. The atrial segments formed by the surgical segregation are electrically isolated and too small to allow the fibrillation to continue. However, the surgical technique is quite
15 traumatic and is unacceptable to a large fraction of those patient's experiencing atrial fibrillation or flutter.

Avital in PCT 95/15115 discloses the use of high frequency electrical energy with a specific intravascular electrophysiological (EP) device to form linear ablations within a patient's atrial chamber to
20 provide results similar to the surgical segregation techniques in terminating atrial fibrillation but with significantly reduced trauma. However, the Avital device cannot always be readily placed a desired location within the patient's atrial chamber and it does not

always provide the necessary contact between the ablating electrodes on the device and atrial tissue at the desired location to generate linear lesions of a requisite length when RF electrical energy is emitted from the electrodes.

- 5 What has been needed is an ablation device and an assembly of such a device with a delivery system which can be readily manipulated within a patient's atrial chamber to generate effective linear lesions at any desired location within the atrial chamber. The present invention satisfies these and other needs.

10

SUMMARY OF THE INVENTION

- This invention is directed to an elongated EP device and to an assembly therewith including a delivery system for the EP device, which is suitable for forming effective linear ablations within a chamber
- 15 of a patient's heart. The lesions from such linear ablations are particularly suitable for eliminating or minimizing atrial fibrillation and flutter by isolating sections of the patient's atrial wall.

- In a broad sense the assembly of the invention comprises a delivery system which includes a delivery sheath with an inner lumen
- 20 extending therein, an elongated open distal section, an elongated support member coextensive at least in part with the elongated open distal section and an elongated EP device disposed within the inner

lumen of the delivery sheath and fixed by its distal end within the distal portion of the delivery sheath. The EP device of the assembly has a plurality of electrodes on the distal section thereof which may be used for both sensing or ablating. The outer maximum dimension of the

5 distal section of the EP device, particularly the outer maximum dimensions of the electrodes, are generally less than about 1.65 mm (5 Fr.), preferably less than about 1.3 mm (4 Fr.). The electrodes of this size provide a much more efficient transfer of electrical energy to the contacting tissue and there is apparently considerably less energy loss

10 to the surrounding fluid contacting the exposed electrode and therefore there is much less power required to form an effective lesion.

Moreover, the electrodes of the present invention provide more narrow and better defined lesions than prior devices while still maintaining adequate lesion depth to electrically isolate the heart sections in a

15 desired fashion.

With the distal tip of the EP device secured within the distal tip of the delivery sheath, longitudinal movement of the EP device slidably disposed within the inner lumen of the delivery sheath causes the distal portion of the EP device to arcuately extend out and away from the

20 open distal section of the delivery sheath. The supporting member in the distal portion of the delivery sheath provides support to the distal end of the EP device and ensures that the distal portion of the EP

device effectively engages the inner surface of the patient's heart chamber along a length thereof so that high frequency (e.g. RF) electrical energy emitted from the electrodes provide effective linear ablation of heart tissue within the patient's heart chamber. Additionally,

5 the electrodes may be used for the collection of electrical signals from the surface of the heart chamber either before the formation of the lesion is formed, to locate the desired region within the patient's heart for treatment, or after the lesion is formed to determine the effectiveness of the lesion in terminating the arrhythmia.

10 Effective detection of electrical activity is desirable in order to accurately locate the arrhythmogenic site so that the linear ablation can be performed for effective lesion formation at a required depth within the wall to isolate the arrhythmogenic site.

In a presently preferred embodiment of the EP device, the distal

15 portion thereof has an inner lumen extending therein with a core member disposed within the inner lumen. The wall of the distal section is formed at least in part of individually insulated electrical conductors which are electrically connected to individual electrodes on the distal section. Preferably the electrical conductors are braided. A plurality of

20 polymer strands formed of nylon, DACRON®) (Dupont) and the like may also be braided either with the electrical conductors as they are braided or braided separately on the exterior of the tubular member

formed by the braided conductors. The proximal ends of the electrical conductors are electrically connected to electrical connectors which facilitate transmission of high frequency electrical energy from a source thereof to individual electrodes (if an extracorporeal electrode is used) or individual pairs of electrodes. The core member is preferably provided with one or more jackets, which are electrically insulating if an electrode is provided on the distal end of the EP device and the core member is used to transmit electrical current to the electrode on the distal end. This design allows for a low profile and flexibility, yet it is sufficiently strong to ensure effective contact between a length of the electrode section and the region of the patient's endocardium where the linear ablation is to occur and an effective formation of an arrhythmia terminating lesion. The EP device may be used by itself or with the assembly described above.

15 In one presently preferred embodiment of the assembly of the invention, the supporting member of the delivery sheath is a metallic ribbon which has an elongated flat surface facing the elongated opening in the distal section of the sheath. It may be made from high strength materials such as stainless steel, pseudoelastic NiTi alloys in an austenite phase (unstressed). The support member is preferably manually shaped into a curved or angled condition to facilitate entry of the distal extremity of the assembly within the patient's heart chamber,

particularly the right atrium, and the proper positioning of the extended distal section of the EP device against the inner surface of the heart chamber. When the distal end is straightened to be introduced into the patient, the austenite phase of the support member then may convert
5 at least in part to a stress-induced martensite phase but upon release of the stress the martensite phase transforms back to the austenite phase.

The inner radius of the extended distal portion of the EP device can be controlled by the length of the elongated opening in the delivery
10 sheath and the distance the EP device is spaced from the support member. The effective length of the elongated open distal section can be controlled by the longitudinal location of the distal end of a second sheath disposed about the exterior of the first sheath. As the distal end of the second sheath extends distally, the effective length of the
15 elongated open distal section is shortened and the radius of curvature of the distal section of the EP device is correspondingly decreased.

These and other advantages of the invention will become more apparent from the following detailed description and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an elevational view, partially in section, of an assembly embodying features of the invention.

Fig. 2 is a transverse cross-sectional view of the assembly shown in Fig. 1 taken along the lines 2-2.

Fig. 3 is a transverse cross-sectional view of the assembly shown in Fig. 1 taken along the lines 3-3.

Fig. 4 is an elevational view, partially in section, of an EP device suitable for use with the assembly shown in Figs. 1-3.

Fig. 5 is a transverse cross-sectional view of the EP device shown in Fig. 4 taken along the lines 5-5.

Fig. 6 is a longitudinal cross-sectional view of an alternative embodiment similar to that shown in Fig. 1 wherein a lumen is provided to deliver fluid to the distal extremity of the assembly.

Fig. 7 is a transverse cross-sectional view of the assembly shown in Fig. 6 taken along the lines 6-6.

Fig. 8 is a longitudinal cross-sectional view of an alternative embodiment similar to that shown in Fig. 6 with a lumen extending from the proximal end of the assembly to the distal end of the assembly.

Fig. 9 is a transverse cross-sectional view of the assembly shown in Fig. 8 taken along the lines 9-9.

Fig. 10 is a transverse cross-sectional view of the assembly shown in Fig. 8 taken along the lines 10-10.

Fig. 11 is an elevational view, partially in section, of another alternative embodiment wherein the delivery sheath is provided with
5 electrodes for sensing and/or ablation.

Fig. 12 is a transverse cross-sectional view of the embodiment shown in Fig. 11 taken along the lines 12-12.

Fig. 13 is an elevational view of another embodiment wherein the EP device of the assembly is provided with an inner lumen for
10 delivery of fluid.

Fig. 14A is a transverse cross-sectional view of the embodiment shown in Fig. 13 taken along the lines 14-14.

Fig. 14B is a transverse cross-sectional view of an alternative embodiment of that shown in Fig. 13 taken along the lines 14-14.

15 Fig. 15 is an elevational view, partially in section, of a distal section of an alternative embodiment wherein the EP device is provided with an inner lumen for passage of fluid coolant.

Fig. 16 is a transverse cross-sectional view taken along the lines 16-16.

20 Fig. 17 is an elevational view, partially in section, of a distal section of an alternative embodiment wherein an outer sheath is disposed about the assembly which is longitudinally movable to control

the effective length of the elongated opening in the distal section of the delivery sheath.

Fig. 18 is an elevational view, partially in section, of an alternative embodiment wherein a longitudinally movable flush sheath
5 is provided about the EP device of the assembly to delivery fluid to desired locations on the distal section thereof.

Fig. 19 is a transverse cross-sectional view of the embodiment shown in Fig. 18 taken along the lines 19-19.

Fig. 20 is an elevational view, partially in section, of an
10 alternative EP device designed for use without being secured to a delivery system.

Fig. 21 is a transverse cross-sectional view of the embodiment shown in Fig. 20, taken along the lines 21-21.

Fig. 22 is an elevational view, partially in section of an
15 alternative EP device similar to the EP device shown in Fig. 20 which has a plurality of thermocouples within the distal section to detect temperature during the procedure.

Fig. 23 is a transverse cross-sectional view of the embodiment shown in Fig. 22, taken along the lines 23-23.

DETAILED DESCRIPTION OF THE INVENTION

Figs. 1-3 schematically depict a mapping/ablation assembly 10 embodying features of the invention which generally comprises a delivery sheath 11 and an elongated EP device 12 slidably disposed within the inner lumen 13 of the delivery sheath 11 with the distal end of the EP device secured within the sheath 11. An adapter 14 is provided on the proximal end of the delivery sheath 11 with a hemostatic valve 15 on the proximal end of the central arm 16 of the adapter and with a flush port 17 in the proximal end of the side arm 18.

10 The delivery sheath 11 has a proximal shaft section 20 which is formed of a braided tubular structure 21 with a polymer impregnate 22 incorporated therein. The braided structure 21 may be formed of high strength filaments 23 (e.g. 6 x 6 strands) such as stainless steel wire with a typical diameter of about 0.003 inch (0.08 mm). The polymer
15 impregnate is preferably a thermoplastic polyurethane such as PEBAX 6333. An inner lining 24 of high strength polymer material such as polyimide may be provided which extends to the start of the distal section 25 of the delivery sheath 11.

A supporting ribbon 26 extends through the distal section 25
20 with the proximal extremity thereof about 5 to about 15 mm being secured to the braided tubular structure 21 by suitable means such as solder or adhesive 27 within the wall of the proximal shaft section 20.

The supporting ribbon 26 is generally about 6 to about 20 cm in total length and has a rectangular transverse cross-section of about 0.003-0.007 inch by 0.01-0.03 inch. The distal extremity of the supporting ribbon 26 is secured to the distal end of the delivery sheath 11 in a similar fashion. As shown in Figs. 1 and 3, the braided tubular structure 21 extends into the distal section 25 of the delivery sheath 11 disposed about the supporting ribbon 26.

The distal section 25 of the delivery sheath 11 has an elongated opening 28 which allows the distal section 30 of the EP device 12 to be extended out and away from the distal section 25 of the delivery sheath 11 when an axial compressive force is applied to the proximal extremity of the EP device which extends out of the patient during the procedure. The length of the elongated opening 28 is generally the same length as the distal section 25, i.e. about 3 to about 20 cm. The width of the elongated opening 28 generally is greater than the diameter of the distal section 31 of the EP device 12 to allow for the ready outward movement of the EP device.

The EP device 12, as shown in Figs. 1 and 4-5 includes a proximal shaft section 30 and a distal shaft section 31. The distal shaft section 31 has a plurality of mapping/ablation electrodes 32 with each of the electrodes electrically connected to separate electrical conductors 33 (shown in Figs. 4-5). The electrodes 32 are preferably

not larger than about 1.5 mm (4 Fr.), usually less than 1.3 mm (3.5 Fr.) in outer transverse dimensions. The electrode length may vary from about 1 to about 6 mm, preferably about 1 to about 3 mm, and the interelectrode spacing may vary from about 0.5 to about 4 mm, preferably about 0.5 to about 2 mm. The electrodes 32 may be in the form of metallic cylindrical bands, helical coils, arcuate bands or ribbons and the like. The only portion of the electrodes 32 which need exposure are those surfaces which are to be in contact with the inner surface of the heart chamber to detect electrical activity or effect a linear ablation.

A suitable EP device 12 shown in detail in Figs. 4 and 5, has proximal and distal shaft sections 30 and 31, an electrical connector 34 on the proximal end of the device and eight electrodes 32 on the distal section 31 which are electrically connected to insulated electrical conductors as in copending application Serial No. 08/188,619, filed on January 27, 1994, which is incorporated herein in its entirety by reference. Core member 35 extends to the distal end of the device which is secured to the distal end of coil 36 by suitable material such as a gold-tin solder (80% Au-20% Sn). The coil 36 is preferably a 90% Pt-10% Ir wire about 0.005 inch in diameter. Polyimide tubing 37, about 0.001 inch thick, jackets the core member 35 proximal to the coil 36 which is in turn covered with a fluoropolymer tube 38 such as THV

200G which is available from 3M. The braided electrical conductors 33 are formed of 36 AWG copper wire with each conductor having a polyimide insulating coating of about 0.0005 inch thick (0.013 mm). An equivalent number of polyester fibers 39 (e.g. Dacron® from Dupont) are braided with the electrical conductors 33. The braided structure formed by the electrical conductors 33 and the polyester strands 39 are covered by an additional fluoropolymer jacket or coating 40, preferably THV 200g made by 3M. The electrodes 32 are helical coils which are preferably formed from 90% Pt-10% Ir wire about 0.005 inch (0.13 mm) in diameter.

The overall length of the delivery sheath 11, excluding the adapter 14, is about 110 to about 130 cm and the outer diameter is about 0.06 to about 0.08 inch (1.5-2.0 mm). The inner lumen 13 is slightly larger than the outer diameter of the EP device 12 and generally is about 0.035 to about 0.055 inch (0.9-1.4 mm). The EP device 12 has a working length of about 110- 155 cm and a total length of about 135 to about 175 including the electrical connector 34.

The assembly of the invention may be introduced into the patient's vascular system, e.g., the femoral vein, percutaneously or by way of a cut-down, advanced therein and through the inferior vena cava until the distal section 25 is disposed within the right atrium. The supporting ribbon 26 in the distal shaft section 31 is shaped into a

curved configuration so that it assumes the curved configuration when unrestrained within the heart chamber. With the supporting ribbon acting as a supporting surface, a compressive force is applied to the proximal extremity of the EP device which extends out of the patient to

5 urge the device in the distal direction, causing the distal shaft section 31 of the EP device 12 to bow outwardly away from the distal section of the delivery sheath 11 and the support ribbon 26 therein. Torquing the proximal section 30 of the delivery sheath 11, which extends out of the patient during the procedure, will cause the distal section 25 thereof to

10 be rotatably displaced within the atrial chamber and allow the EP device 12 to be bowed outwardly in a wide variety of directions so electrical activity can be detected in a linear fashion and heart tissue can be linearly ablated at a number of locations within the chamber. When sensing electrical activity essentially all of the electrodes 32 can

15 be simultaneously employed, but, when performing a linear ablation, the typical procedure is to direct the RF current to one or two electrodes at the most distal end of the EP device to perform the first ablation and then continue proximally one or two electrodes at a time until a linear ablation of desired length is obtained in the atrial chamber.

20 This reduces the overall power requirements for the assembly.

The electrodes 32 heat up due to the conductive heat transfer from the tissue being ablated and it is preferred to bath the electrodes

with cooling fluid during the procedure to minimize the formation of thrombus. While not shown in the drawings, thermocouples, thermistors or other temperature sensing means may be incorporated into the wall of the EP device 12 to detect the temperature of the electrodes or device wall. The flow of cooling fluid may be controlled to bathe the distal shaft section 31 of the EP device 12 based upon the temperature sensed by the temperature sensing means.

After the ablation, the electrodes 32 can be employed to detect electrical activity to ensure that the ablation has been effective in terminating the fibrillation or flutter. The electrodes 32 are much smaller in diametrical dimensions than prior ablation electrodes which are usually about 1.5 mm or larger. Surprisingly, it has been found that the much smaller electrodes of the present invention provide effective ablation through the atrial wall without the power requirements of the prior electrodes. The elongated lesion formed by the linear ablation with the smaller electrodes, while much thinner than lesions formed with the prior larger electrodes, is quite effective in segregating heart tissue so as to terminate the fibrillation or flutter. Typically, the elongated lesion formed with the device of the present invention is about 3 to about 12 mm, usually about 5 to about 10 mm, in width.

Figs. 6 and 7 illustrate an alternative embodiment to that shown in Figs. 1-3 wherein a second lumen 41 is provided within the distal

section of the delivery sheath in order to pass flushing or cooling fluids to the distal extremity of the sheath. The spacing between the exterior of the EP device 12 and the inner surface of the inner lumen 13 of the delivery sheath 11 is minimized at location 42 so that a significant
5 portion of fluid passing through the inner lumen 13 will pass through port 43 into the inner lumen 41. A discharge port 44 is provided in the distal end of the delivery sheath 11 for discharge of fluid from the inner lumen 41.

Figs. 8-10 illustrate another embodiment similar in function to
10 that shown in Figs. 7-8 which has a second lumen 45 extending the length of the delivery sheath 11 which is in fluid communication with a second side arm 46 of the adapter 14. The other portions of the embodiment are similar to the embodiment shown in Figs. 7-8 and are similarly numbered.

15 Figs. 11-12 depict yet another embodiment similar in most regards to that shown in Fig. 1 except that the delivery sheath 11 is provided with a plurality of electrodes 47 on the distal section 25 and at least one electrode 48 on the proximal shaft section 20. In this embodiment, the surface of the electrodes 47 on the inside of the
20 curved distal section 25 need to be exposed. The electrodes 47 and 48 may be helical coils as shown or cylindrical tubes or arcuate ribbon or bands provided on the inside curve of the distal section 25.

Individual electrical conductors (not shown) may be incorporated into the braided tubular structure 21 and electrically connected by their distal ends to the electrodes 47 and 48 and by their proximal ends to one or more electrical connectors configured to be electrically
5 connected to a high frequency electrical energy source.

Another alternative embodiment of the invention is shown in Figs. 13, 14A and 14B wherein the EP device 12 is provided with an inner lumen 49 for fluid delivery. An adapter 50 is secured to the proximal end of the EP device 12 to facilitate introduction of fluid to the
10 inner lumen 49. In Fig. 14A the lumen 49 is off-set from the electrical conductors 51 which are braided about the core 52, whereas, in Fig. 14B the lumen 49 is formed by the braided conductors 51 within a polymer matrix 53. The embodiment of Fig. 14B does not have a core member 52 as in Fig. 14A. A discharge port 54 is provided in the distal
15 end of the EP device 12 which is in fluid communication with the inner lumen 49.

Alternative electrode details are illustrated in Figs. 15 and 16 where the electrodes 32 are formed by a pair of inner and outer coils 55 and 56 which are secured together at each end by solder, adhesive
20 or the like. The electrodes 32 are cooled by fluid flowing through the inner lumen 49. The coils may be expanded in the longitudinal direction to allow passage of fluid therethrough. A passageway (not

shown) must be provided through the wall of the EP device to facilitate the passage of fluid. A single coil may be used for each electrode rather than a pair of coils 55 and 56 as shown.

In some instances it is desirable to change the curvature of the distal shaft section 31 of the EP device 12 when the distal end of the device is within the heart chamber to provide a better fit between the distal shaft section 31 and the inner surface of a heart chamber. To facilitate such changes, an outer sheath 57 may be provided about the exterior of the delivery sheath to effectively shorten the elongated opening 28 in the distal section 25 of the delivery sheath 11 as shown in Fig. 16. By shortening the elongated opening 28 the radius of curvature is reduced, as shown in phantom in Fig. 16. Fluid may be passed through the inner lumen 58 of the sheath 57 to cool the electrodes 32 during delivery of RF electrical energy. A variety of other means may be employed to effectively shorten the elongated opening 28.

Figs. 17 and 18 illustrate another method of cooling the electrodes 32 on the distal section of the EP device 12 where a flushing sheath 59 is slidably disposed about the EP device. In this embodiment, the sheath 59 can be longitudinally moved along the shaft of the EP device to expose one or more electrodes 32. Fluid passing over the exposed electrode(s) while electrical energy is being delivered

will cool the electrodes sufficiently to avoid thrombus formation.

Usually, electrical energy is not directed to the entire array of electrodes at the same time due to the rather large power requirements for such delivery. Electrical energy is preferably delivered to one or two
5 of the most distal electrodes while fluid is delivered thereto until the lesion of desired length is formed. The sheath 59 is then pulled proximally to expose additional electrodes 32, electrical energy is delivered to one or two additionally exposed electrodes while cooling fluid flows out of the distal end of the sheath 59. This procedure
10 continues sequentially delivering electrical energy to the more proximal electrodes until a linear ablation of the desired length is formed in the wall of the patient's heart. The individual electrodes 32 may be used to detect electrical activity after each individual ablation and after the entire linear ablation procedure has been completed to determine if the
15 fibrillation or flutter has been terminated.

Figs. 20 and 21 illustrate an embodiment of an EP device which may be used by itself to form linear ablations within a patient's heart chamber, particularly the atrial chamber. It is for the most part similar to the embodiment shown in Figs. 4 and 5 except for the absence of
20 the coil on the distal tip of the device and the corresponding parts are similarly numbered. The catheter 30 has a distal shaft section 31 which is provided with a plurality of electrodes 32 formed by helical

coils of conductive metallic material such as an alloy of 90% platinum and 10% iridium. A core member 35 formed of 304 stainless steel is disposed within the catheter 30 and is provided with a first insulating coating or jacket 37 which is preferably formed of polyimide and an
5 outer jacket 38 formed of a fluoropolymer such as THV 200G. Electrical conductors 33 are braided onto the outer jacket 38 and polymer strands 39 (e.g. Dacron) are braided onto the braided conductors 33. The ends 60 of the metallic coils forming the electrodes 32 are electrically connected to individual conductors 33 by a suitable
10 electrically conducting solder such as 80Au%-20%Sn. The insulation on the electrical conductors 33 is removed at the site where the ends 60 of the coil contact the electrical conductors 33. A rounded electrode 61, formed of suitable material such as platinum, is provided at the distal tip of the catheter 30 which is secured to the tapered end of the
15 core member 35 by a suitable electrical conducting solder 62 (80% Au20%Sn). An electrical conductor 63 is provided to direct electrical current to the electrode 61. Suitable insulation 64 (e.g. Pebax 4033) separates the electrode 61 from the electrode 32 and the braided electrical conductors 33. The distal shaft section is flexible enough to
20 be advanced through the patient's vasculature to the patient's heart chamber and yet it has sufficient strength to be pressed against the

patient's endocardium to provide contact to effectively form the elongated lesion.

A similar embodiment is shown in Figs. 22 and 23 which has thermocouples 65 located between the outer jacket 38 and the braided
5 conductors 33. The device is otherwise similar to the prior embodiment and is provided with the same reference numbers. As shown best in Fig. 23, the thermocouples 65 are preferably T type thermocouples joining a copper thermocouple conductor wire 66 and Constantan thermocouple conductor wire 67. Preferably, a thermocouple 65 is
10 provided beneath each electrode 32 so that the electrical power delivered to each electrode can be controlled by a suitable device (not shown) to control the temperature in a desired manner.

In the embodiments shown in Figs. 20-23 the electrodes are about 2 to about 4 mm in length, typically about 3 mm, and have an
15 interelectrode spacing of about 1 to about 3 mm, typically about 2 mm. The distal shaft section 31 is less than about 5 French (mm), preferably less than 4.5 French (mm). The length of the distal shaft section 31 having electrodes 32 is about 10 to about 50 cm and preferably about 30 to about 45 cm. Both embodiments of Figs. 20-23 may be
20 employed with the assembly described in the previously discussed embodiments.

The electrical connector 34 on the proximal ends of the embodiments described herein may be commercially available electrical connectors such as Part No. PAB-MO8-GLA39J or PAB-MO8-TLA39J for an eight pin connector or Part No. PAB-MO8-GLA39A for a connector with a greater number of pins, e.g. 9-16. The above connectors are available from Lemo USA, Inc. in Santa Rosa, CA. Suitable connectors for accessory cables connectable to the above connectors include PRB-MO8-GLL65J for eight pin connectors and PRB-MO8-GI165A for connectors with more than eight pins. The latter connectors are also available from the same source.

While the invention has been described herein in terms of certain preferred embodiments directed to the detection and treatment of atrial fibrillation and flutter, those skilled in the art will recognize that the invention may be employed in a wide variety of procedures where an elongated narrow lesion is to be formed. Moreover, although individual features of embodiments of the invention may be shown in some of the drawings and not in others, those skilled in the art will recognize that individual features of one embodiment of the invention can be combined with any or all the features of another embodiment. A variety of modifications and improvements may be made to the present invention without departing from the scope thereof.

WHAT IS CLAIMED IS:

1. An intravascular assembly for forming a lesion within a patient's heart, comprising:

5 a) an elongated delivery member having proximal and distal ends, an inner lumen extending therein to the distal end, an elongated distal section which has an opening in communication with the inner lumen and a support means for at least part of the open distal section; and

10 b) an elongated electrophysiological device disposed within the inner lumen of the delivery member having a plurality of electrodes on a distal portion thereof which is disposed within the open distal section and having electrical conductors with proximal and distal ends which are electrically connected by their distal ends to electrodes and by their proximal ends to
15 electrical connector means.

2. The intravascular assembly of claim 1 wherein the distal section is shaped to facilitate entry and positioning within the patient's heart chamber.

3. The intravascular assembly of claim 1 wherein the
20 support means within the distal section is a metallic ribbon.

4. The intravascular assembly of claim 3 wherein the metallic ribbon has a flat surface facing the opening in the distal section.

5. The intravascular assembly of claim 1 wherein the electrodes on the distal portion of the electrophysiological device are not more than 1.35 mm in diameter.

6. The intravascular assembly of claim 1 including a longitudinally movable sheath disposed about the delivery member to control the length of the distal section which is uncovered.

10 7. The intravascular assembly of claim 6 wherein the outer sheath has a curved distal extremity.

8. The intravascular assembly of claim 1 including a longitudinally movable sheath disposed about the EP device having a proximal end configured to be connected to a source of fluid and a
15 distal end extending over the distal portion of the EP device.

9. The intravascular assembly of claim 1 including a second inner lumen extending within at least the distal section of the elongated delivery member to a discharge port in the distal end of the elongated delivery member.

10. The intravascular assembly of claim 9 wherein the second inner lumen extends from the proximal end of the elongated delivery member to the distal end thereof.

11. The intravascular assembly of claim 1 wherein the
5 elongated delivery member is provided with at least one electrode on the distal section thereof.

12. The intravascular assembly of claim 1 wherein the distal section of the elongated delivery member is provided with a lumen for delivery of cooling fluid to the distal end of the assembly.

10 13. The intravascular assembly of claim 1 2 wherein the lumen for delivery of the cooling fluid extends to the proximal end of the assembly.

14. The intravascular assembly of claim 3 wherein a multi-arm adapter is provided on the proximal end of the assembly which has
15 an arm with an inner lumen in fluid communication with the inner lumen of the delivery assembly for delivery of cooling fluid.

15. An EP type catheter for use within a patient's heart, comprising:

a) an elongated shaft having proximal and distal
20 ends, an inner lumen extending therein;

- b) a distal shaft section having a maximum outer dimension less than 1.65 mm, a plurality of longitudinally disposed electrodes on an exterior portion thereof with the electrodes having an interelectrode spacing with an adjacent electrode which is not greater than the length of the electrode, and a plurality of individually insulated electrical conductors which are each electrically connected to an individual electrode; and
- c) electrical connector means electrically connected to the proximal ends of the electrical conductors.
- 5
- 10

16. The EP type catheter of claim 18 including a core member extending within the inner lumen of the elongated shaft.

17. The EP type catheter of claim 19 wherein the electrical conductors are disposed about the core member.

15 18. The EP type catheter of claim 20 wherein the electrical conductors form at least part of an outer wall of the distal shaft section.

19. The EP type catheter of claim 18 wherein the electrical connector means is electrically connected to a source of high frequency electrical energy.

20. The EP device of claim 18 wherein the electrodes are about 2 to about 4 mm in length.

21. The EP device of claim 18 wherein the electrodes are longitudinally spaced from an adjacent electrode a distance of about 1
5 to about 3 mm.

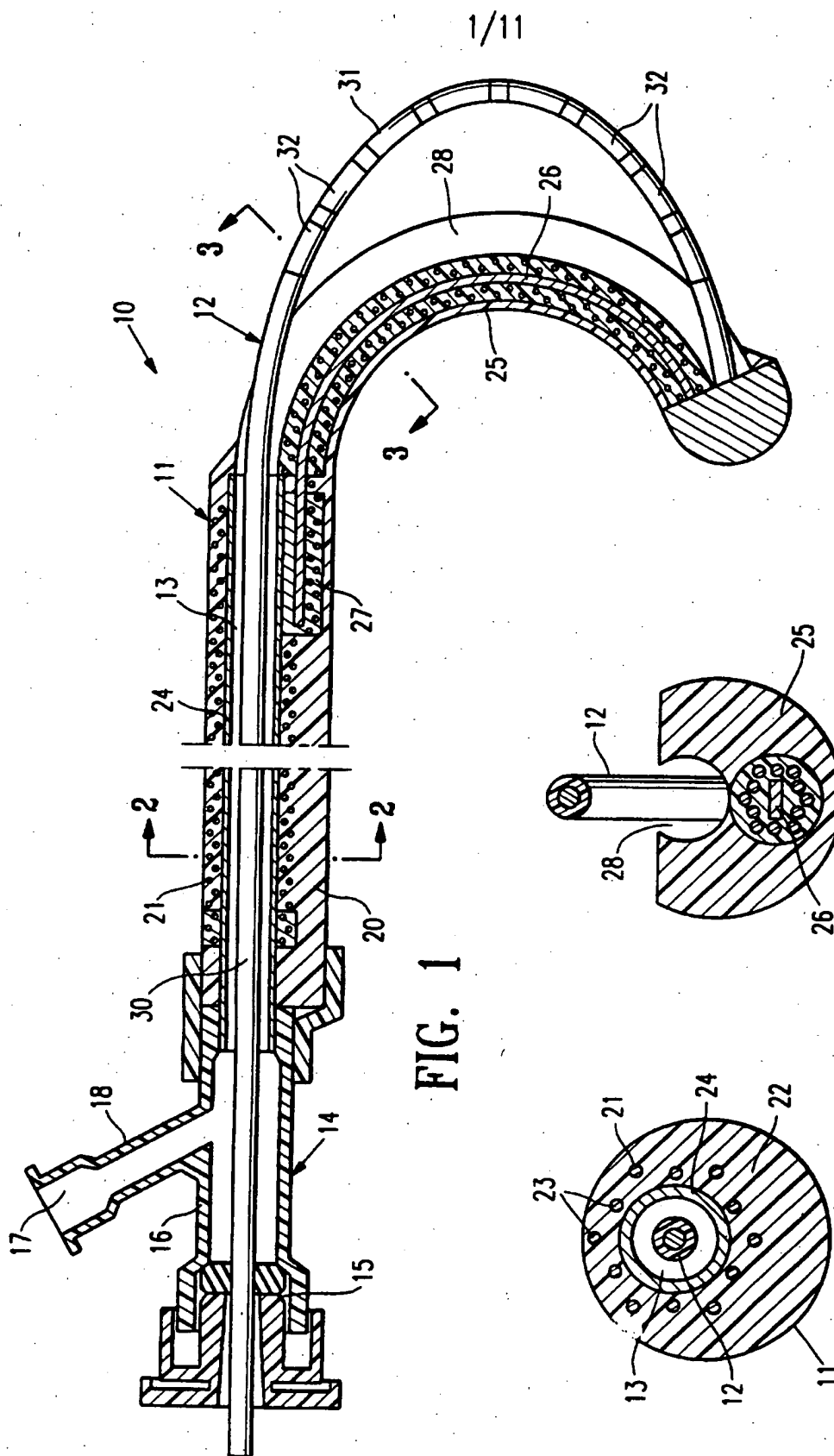


FIG. 1

FIG. 2

FIG. 3

2/11

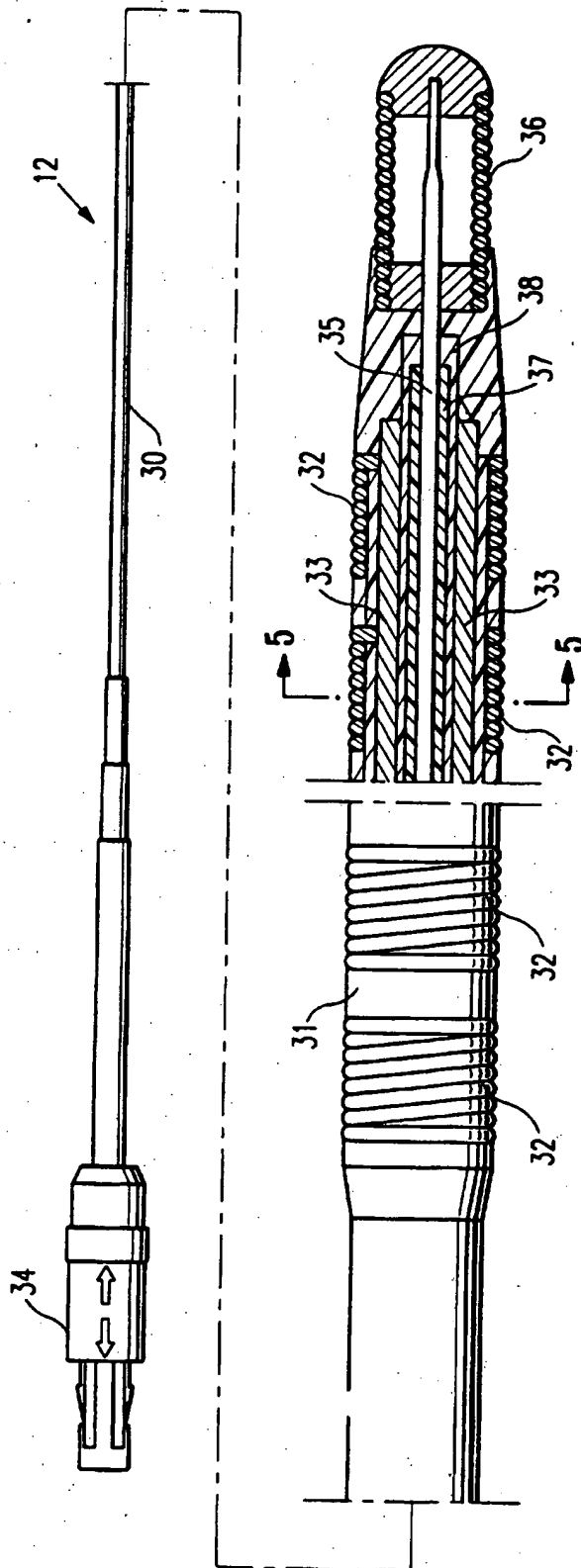


FIG. 4

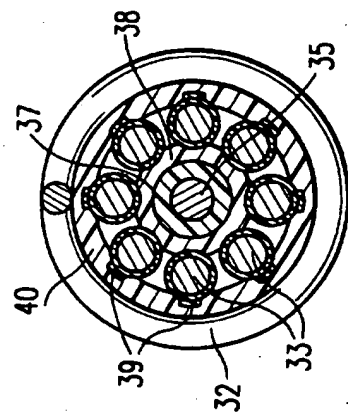


FIG. 5

3/11

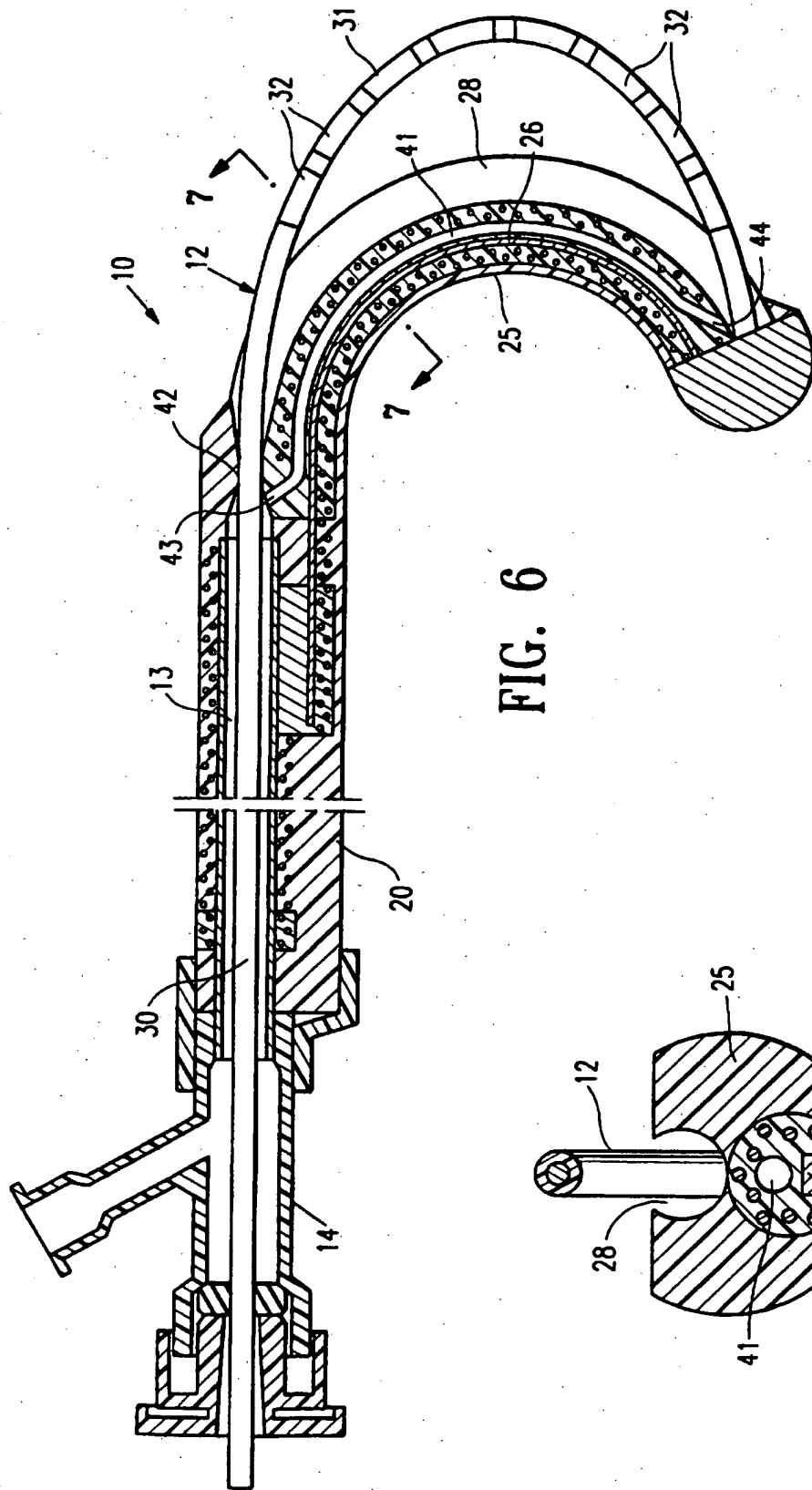


FIG. 6

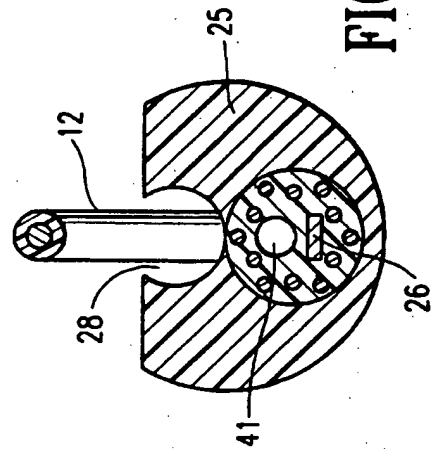


FIG. 7

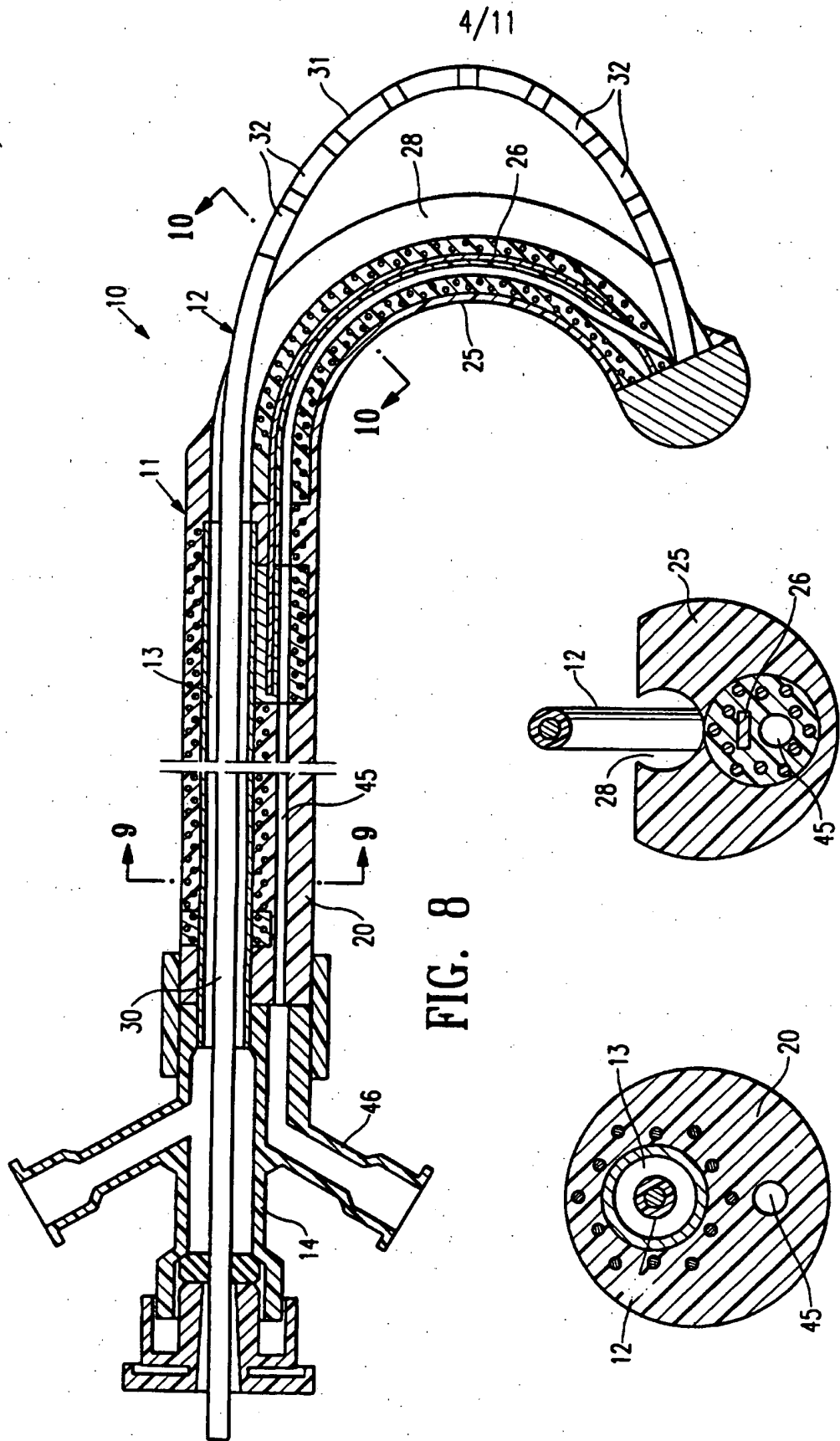


FIG. 8

FIG. 9

FIG. 10

5/11

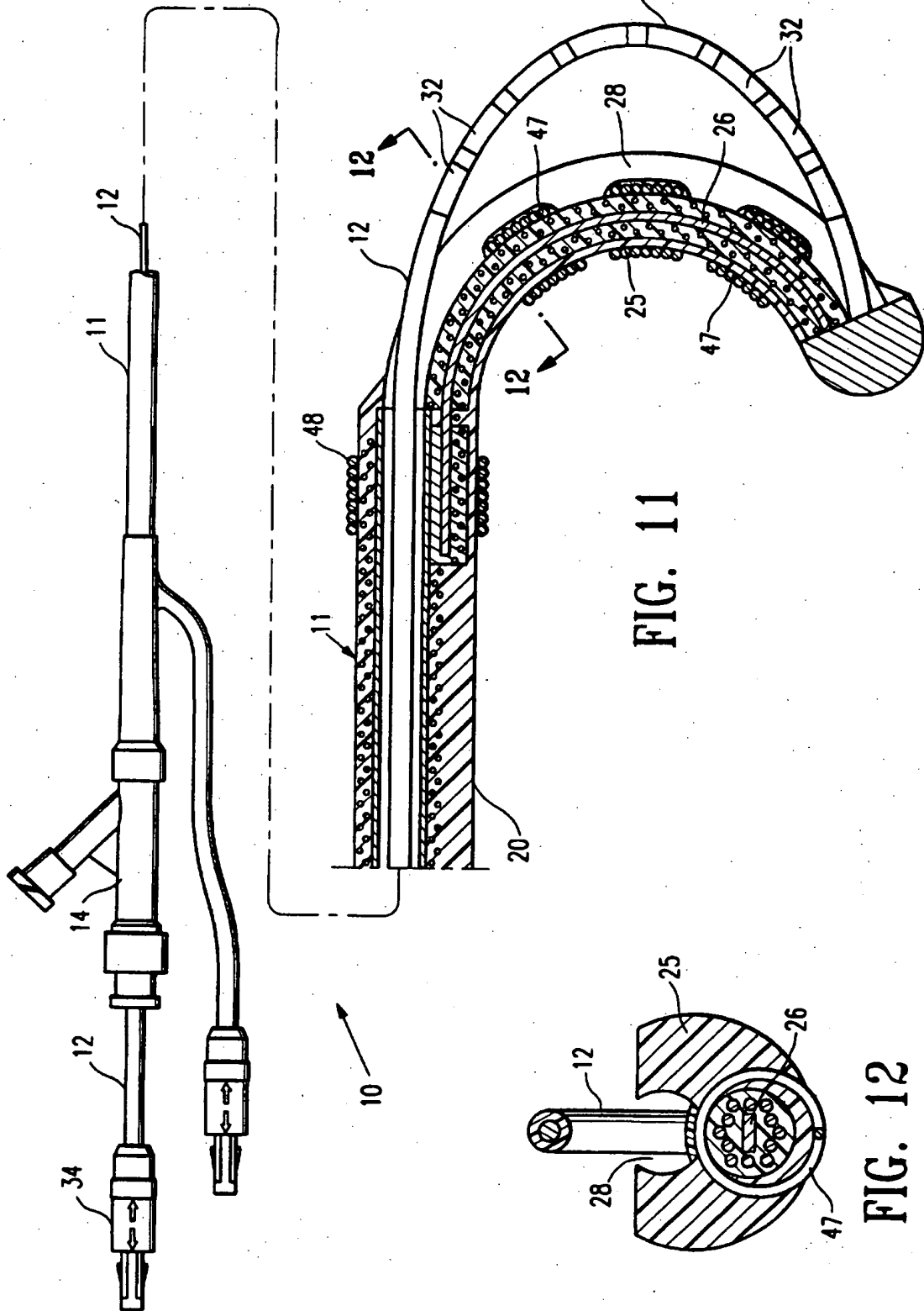


FIG. 11

FIG. 12

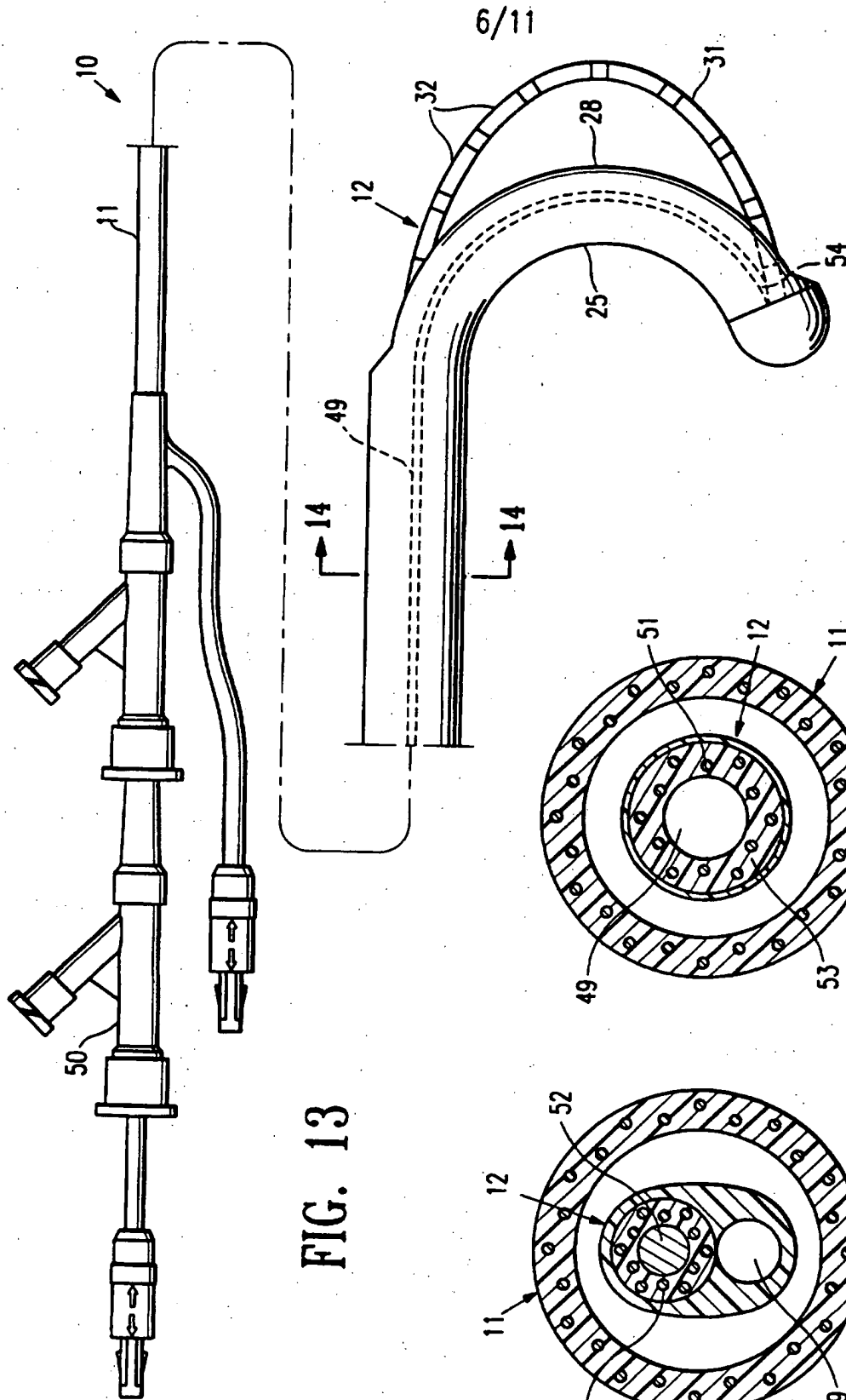


FIG. 13

FIG. 14B

FIG. 14A

7/11

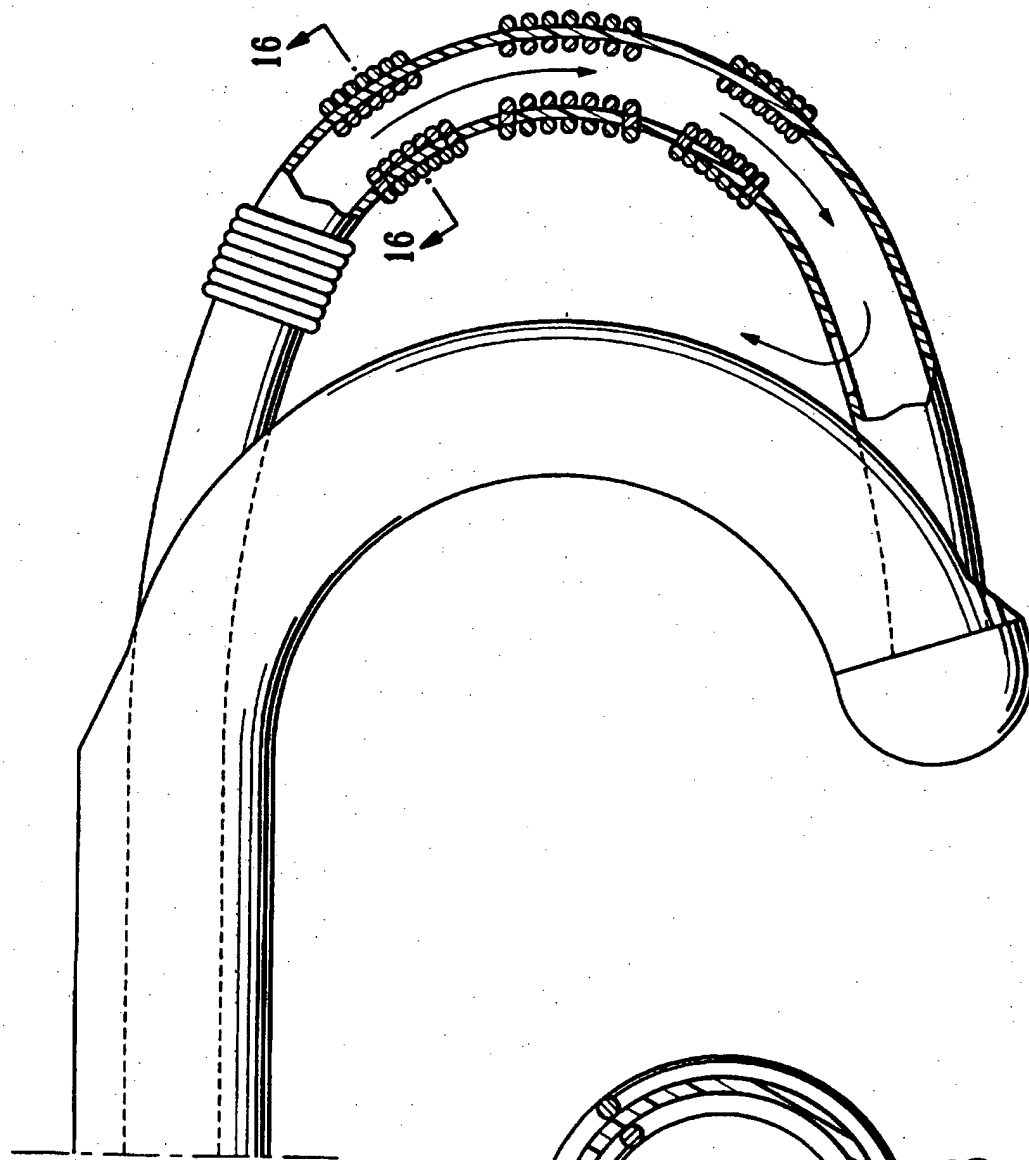


FIG. 15

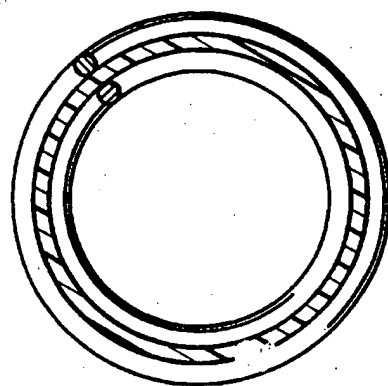


FIG. 16

8/11

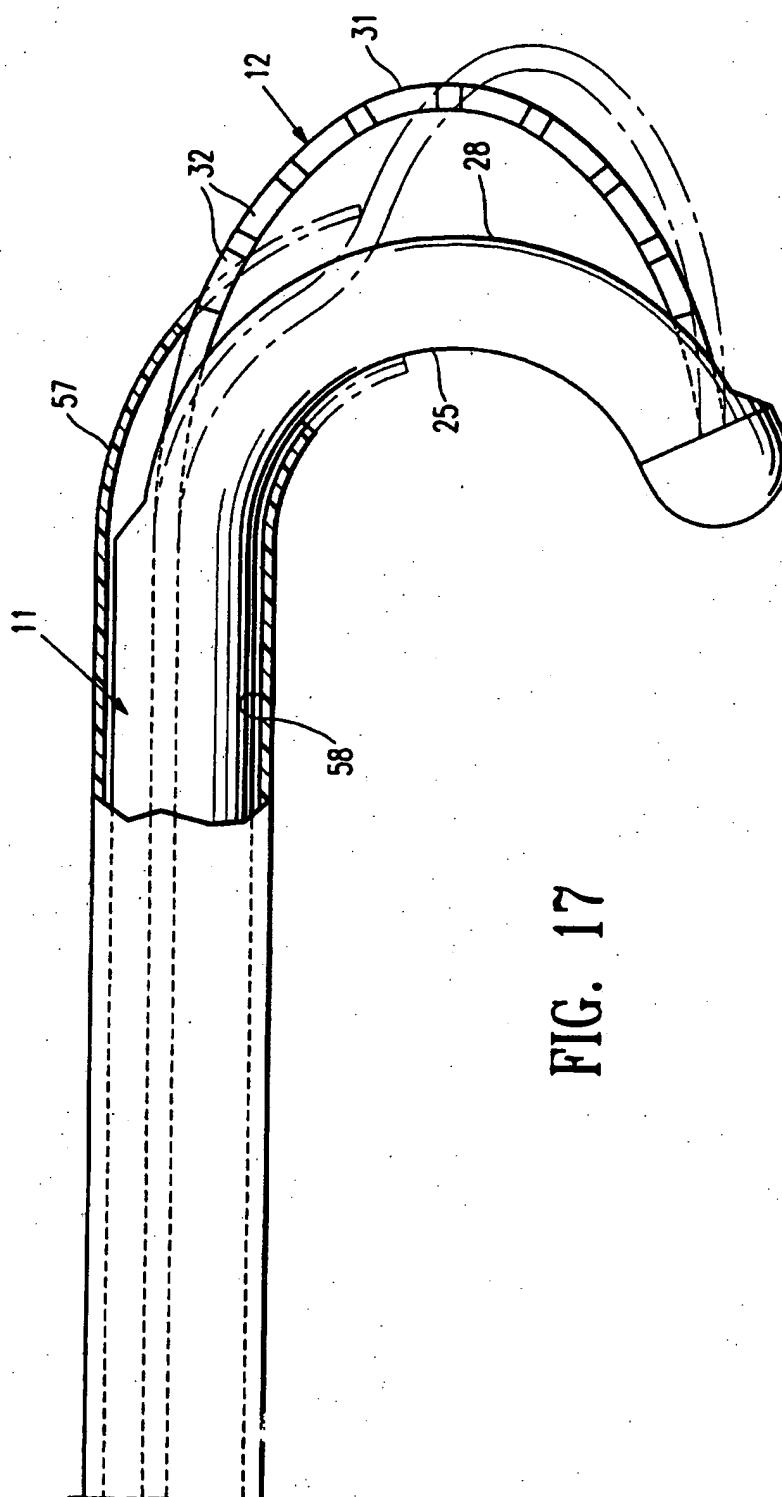


FIG. 17

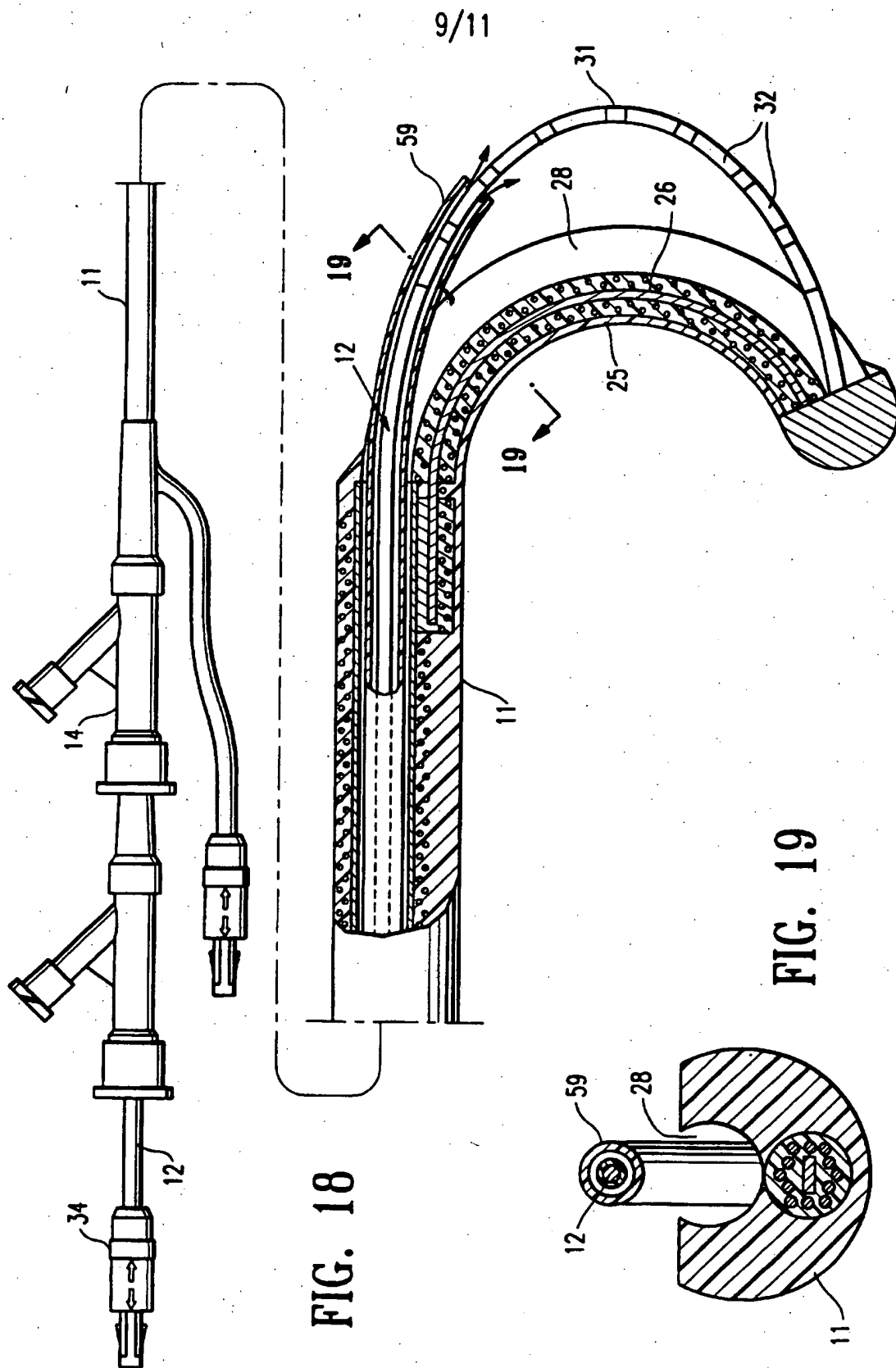


FIG. 18

FIG. 19

10/11

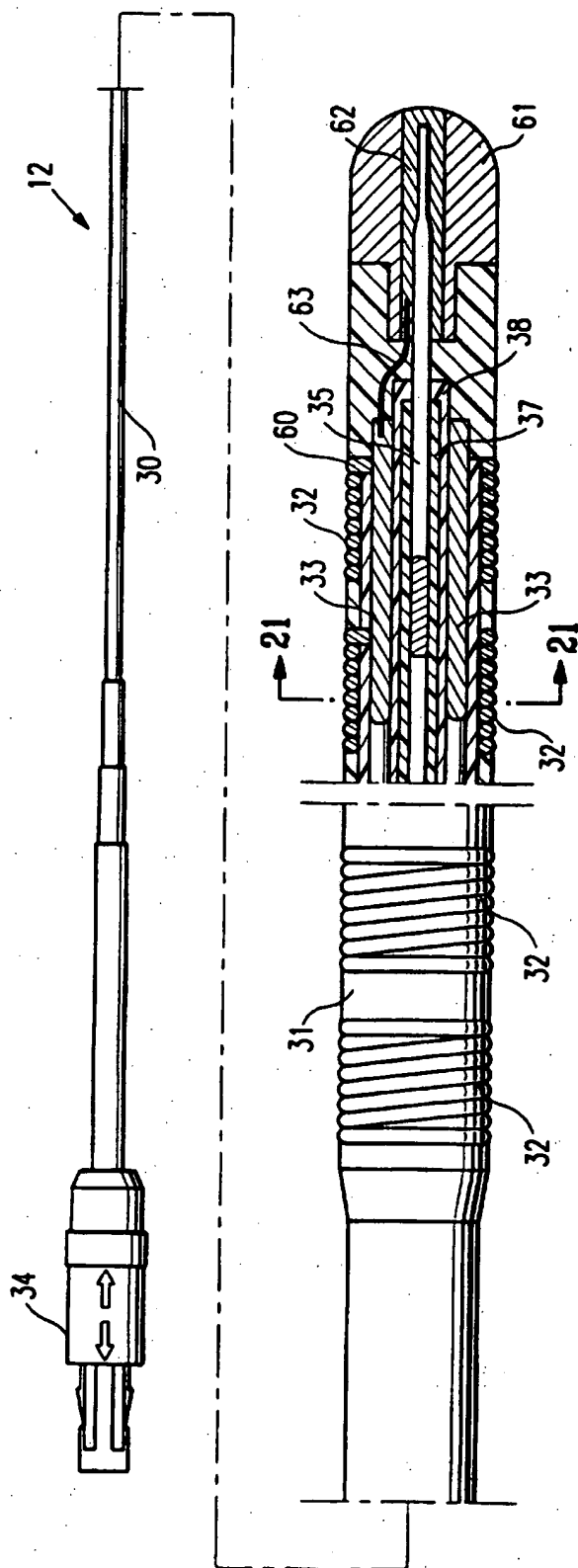


FIG. 20

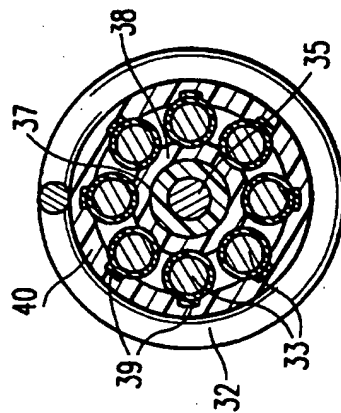


FIG. 21

11/11

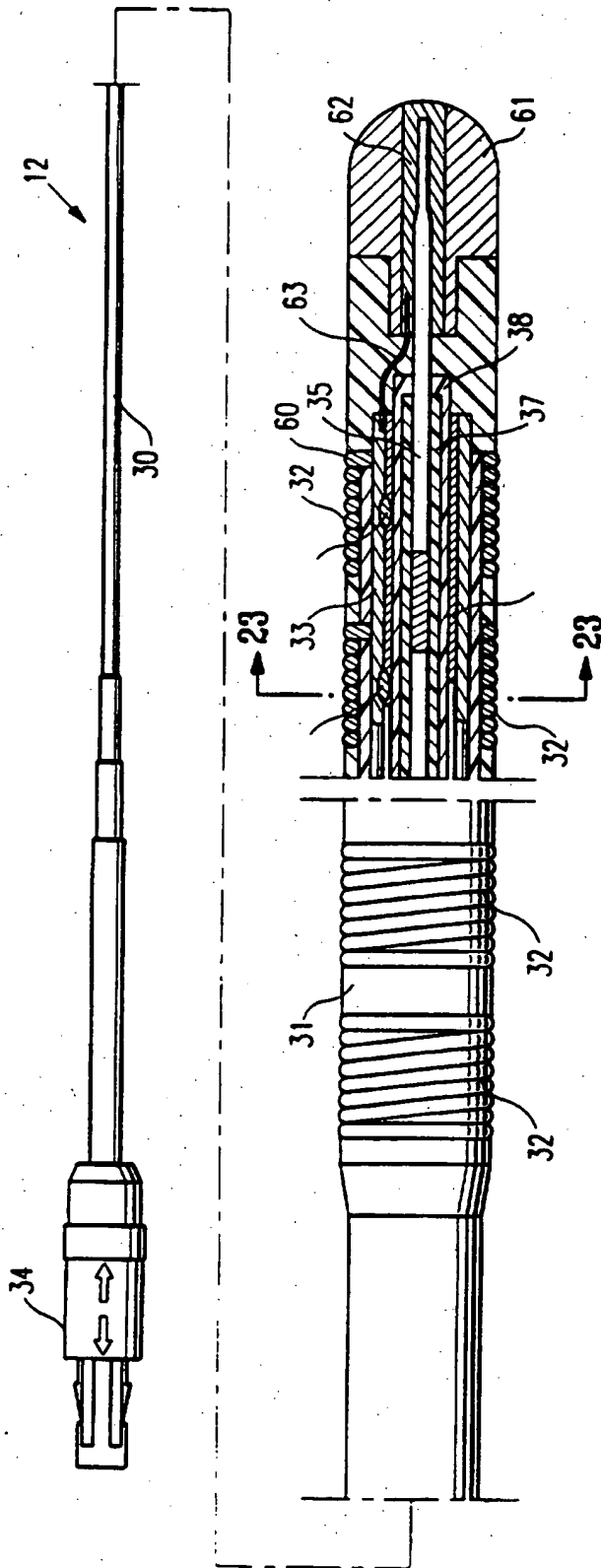


FIG. 22

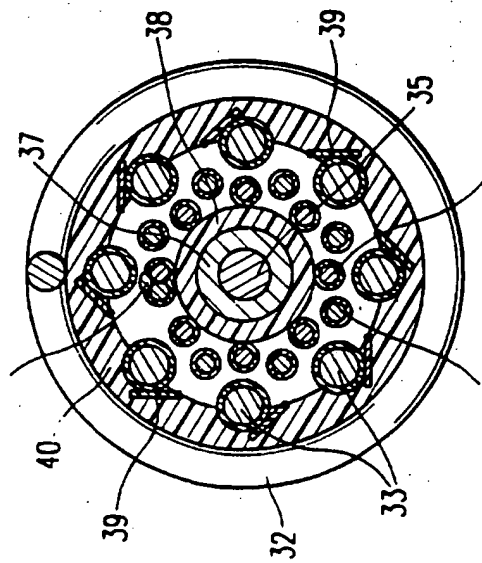


FIG. 23

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



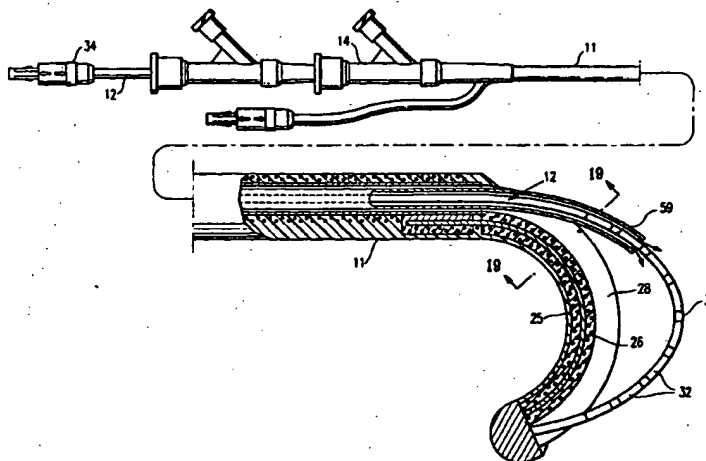
(43) International Publication Date
16 October 1997 (16.10.1997)

PCT

(10) International Publication Number
WO 97/37607 A3

- (51) International Patent Classification⁶: **A61B 17/39** (74) Agents: LYNCH, Edward, J.; Heller Ehrman White & McAuliffe, 525 University Avenue, Palo Alto, CA 94301-1900 et al. (US).
- (21) International Application Number: **PCT/US97/05714**
- (22) International Filing Date: **8 April 1997 (08.04.1997)** (81) Designated States (*national*): AU, CA, JP.
- (25) Filing Language: **English** (84) Designated States (*regional*): European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
- (26) Publication Language: **English**
- (30) Priority Data:
08/629,057 8 April 1996 (08.04.1996) US
08/659,769 6 June 1996 (06.06.1996) US
- Published:
— With international search report.
- (71) Applicant: **CARDIMA, INC.** [US/US]; 47266 Benicia Street, Fremont, CA 94538 (US).
- (88) Date of publication of the international search report:
25 May 2001
- (72) Inventor: **SCHAER, Alan, K.**; 10162 Alpine Drive #B, Cupertino, CA 95014 (US).
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: **LINEAR ABLATION DEVICE AND ASSEMBLY**



(57) Abstract: An intravascular device for the formation of linear lesions which has particular utility in the treatment of atrial fibrillation and flutter. The intravascular device has an outer delivery sheath (11) with a distal section (25) which has an elongated opening (28) and a support member (26) coextending with the opening (28). An EP device (12) having a plurality of electrodes (32) on its distal portion (31) is slidably disposed within the inner lumen (13) of the delivery sheath (11) but it is secured by its distal end within the distal extremity of the delivery sheath (11) at least while in operation. In this manner an axial force in the distal direction on the proximal extremity of the EP device (12), which extends out of the patient during the procedure, will cause the distal portion of the EP device (12) to arch outwardly out of and away from the distal section (25) of the delivery sheath (11) and engage the surface of the patient's heart chamber. High frequency, e.g. RF, electrical energy delivered to the electrodes (32) on the distal shaft section (31) of the EP device (12) will form a linear lesion which terminates the fibrillation or flutter.

WO 97/37607 A3

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/05714

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|----------------------------------|
| X Y | WO 94 16619 A (CARDIMA INC) 4 August 1994 see abstract; figures 9-11 see page 11, line 19 - page 15, line 25 & US 5 509 411 A (LITTMAN ET AL.) cited in the application --- | 1,5,11 2,3, 6-10, 12-14 |
| Y | EP 0 554 722 A (MAHURKAR SAKHARAM DHUNDIRAJ ;MAHURKAR SMRITI S (US)) 11 August 1993 see abstract; figures 1-6 see column 5, line 19 - column 7, line 19 --- | 2,3,9, 10,12-14 |
| Y A | WO 95 34259 A (DESAI ASHVIN H) 21 December 1995 see abstract; figures 17,18 see page 19, line 15 - page 21, line 27 --- | 6-8 12-14 |
| | -/- | |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

8 October 1997

Date of mailing of the international search report

29.10.97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Zeinstra, H

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 97/05714

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-----------------------|
| A | WO 95 10322 A (EP TECHNOLOGIES) 20 April 1995 see abstract; figures 17-30 see page 19, line 20 - page 23, line 4 see page 29, line 2 - line 35 --- | 1,12-14 |
| A | EP 0 609 182 A (XTRUDE SRL) 3 August 1994 see abstract; figures see column 3, line 41 - column 6, line 55 --- | 1 |
| A | WO 95 15115 A (AVITALL BOAZ) 8 June 1995 cited in the application see abstract; figures 1-7 see page 7, line 9 - page 9, line 13 --- | 1 |
| X | WO 92 19167 A (MENTOR O & O INC) 12 November 1992 see abstract; figures 1,2,5 see page 5, line 29 - page 8, line 2 see page 8, line 27 - page 9, line 4 see page 13, line 1 - line 14 --- | 15-19 |
| A | US 5 341 807 A (NARDELLA) 30 August 1994 ----- | |

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 97/05714

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims 1-14
Define an intravascular assembly with a support means,
2. Claims 15-21
Define an EP catheter with a small interelectrode spacing.

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.

PCT/US 97/05714

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---------------------|----------------------------|---------------------|
| WO 9416619 A | 04-08-94 | AU 6233094 A | 15-08-94 |
| | | AU 6233594 A | 15-08-94 |
| | | AU 6233694 A | 15-08-94 |
| | | CA 2154772 A | 04-08-94 |
| | | CA 2154773 A | 04-08-94 |
| | | CA 2154774 A | 04-08-94 |
| | | EP 0682502 A | 22-11-95 |
| | | EP 0681450 A | 15-11-95 |
| | | EP 0681451 A | 15-11-95 |
| | | JP 8506034 T | 02-07-96 |
| | | JP 8506251 T | 09-07-96 |
| | | JP 8506252 T | 09-07-96 |
| | | WO 9416632 A | 04-08-94 |
| | | WO 9416618 A | 04-08-94 |
| | | US 5645082 A | 08-07-97 |
| | | US 5509411 A | 23-04-96 |
| | | US 5645064 A | 08-07-97 |
| EP 0554722 A | 11-08-93 | AT 123657 T | 15-06-95 |
| | | CA 2030638 A,C | 11-07-91 |
| | | DE 69020133 D | 20-07-95 |
| | | DE 69020133 T | 21-09-95 |
| | | EP 0440992 A | 14-08-91 |
| | | US 5374245 A | 20-12-94 |
| | | US 5221255 A | 22-06-93 |
| WO 9534259 A | 21-12-95 | US 5562703 A | 08-10-96 |
| | | AU 3137495 A | 05-01-96 |
| | | US 5662680 A | 02-09-97 |
| WO 9510322 A | 20-04-95 | US 5549661 A | 27-08-96 |
| EP 0609182 A | 03-08-94 | IT 1266217 B | 27-12-96 |
| | | AT 151250 T | 15-04-97 |
| | | DE 69402447 D | 15-05-97 |
| | | US 5482037 A | 09-01-96 |
| WO 9515115 A | 08-06-95 | US 5487385 A | 30-01-96 |
| | | AU 1265495 A | 19-06-95 |
| | | CA 2177982 A | 08-06-95 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/05714

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---------------------|----------------------------|---------------------|
| WO 9515115 A | | EP 0731665 A | 18-09-96 |
| WO 9219167 A | 12-11-92 | AU 2024192 A | 21-12-92 |
| US 5341807 A | 30-08-94 | CA 2139312 A | 06-01-94 |
| | | EP 0648087 A | 19-04-95 |
| | | JP 8505291 T | 11-06-96 |
| | | WO 9400050 A | 06-01-94 |